

REMARKS/ARGUMENTS

This paper is filed in response to the Office Action pending for the subject application. Pending in the application are claims 1-17, with claims 12-17 withdrawn.

In the Office Action, the Specification is objected to as allegedly failing to provide proper antecedent basis for the claimed subject matter. Claim 1 stands objected to because of alleged informalities. Claims 2-3 stand rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter. Claim 4 stands rejected under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the written description requirement and under 35 U.S.C. §112, second paragraph, for allegedly being indefinite. Claims 1-4 stand rejected under 35 U.S.C. §102 for allegedly being anticipated by Wilson (U.S. Pat. No. 6,656,189 B1 to Wilson et al.). Claims 5-11 stand rejected under 35 U.S.C. §103 for allegedly being obvious in view of Wilson.

In the response, claims 1, 6 and 8-11 are amended, claims 2-3, 5 and 7 are cancelled, and claims 18-20 are new. Support for the amendments and the new claims is in, for example, the original disclosure. No new matter is claimed. After entry of this response, the claims pending in the application are 1, 4, 6, 8, 9, 10, 11, 18, 19, 20. All amendments are made without prejudice.

The Applicant has considered the Office Action, and offers the following in response.

Specification

The Specification is objected to as allegedly failing to provide proper antecedent basis for the claimed subject matter. Specifically, the Office Action alleges that paragraph [0099] contains a typographical error, claim 2 includes a term "*external viewing apparatus*", which the Office Action alleges is not referenced in the Specification, and the Office Action alleges that claim 4 includes terms/limitations for which there is no proper description in the disclosure.

Applicant respectfully traverses the rejections. However, to expedite prosecution, paragraph [0099] has been amended to correct the typographical error indicated in the Office Action. Claim 2 is cancelled, rendering the rejection of the claim moot, and claim 4 is amended herein and includes features supported by the disclosure.

Withdrawal of the objection is respectfully requested.

Claim Objections

Claim 1 is objected to for containing the word "*centre*". Although applicant traverses the objection, claim 1 is amended to recite "*center*" to expedite prosecution. Withdrawal of the objection is respectfully requested.

35 U.S.C. §112

Claims 2-3

Claims 2-3 stand rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter. The Office Action alleges that it is unclear whether the recited structure, material or acts are sufficient for performing the claimed function. Applicant respectfully traverses the rejection. However, solely for the purposes of expediting prosecution, Applicant cancels claims 2-3 herein, and incorporates their features into claim 1 such that they comply with 35 U.S.C. §112, and may be treated under 35 U.S.C. §112, sixth paragraph.

Claim 4

Claim 4 stands rejected under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the written description requirement and under 35 U.S.C. §112, second paragraph, for allegedly being indefinite. In particular, the Office Action alleges that there is no written description what this sensor is or what it entails, and that allegedly it is not clear what exactly the interface is, or what the output of the external viewing apparatus is. Although Applicants respectfully

traverse the rejection, claim 4 is amended herein as discussed previously solely for purposes of expediting prosecution, and complies with 35 U.S.C. §112.

Applicant respectfully requests withdrawal of the 35 U.S.C. §112 rejection of these claims.

35 U.S.C. §102

Claims 1-4

Claims 1-4 stand rejected under 35 U.S.C. §102 for allegedly being anticipated by Wilson (U.S. Pat. No. 6,656,189 B1 to Wilson et al). The Applicant respectfully traverses the rejection. However, solely to expedite prosecution, claim 1 is amended to recite:

1. An automatic pointing apparatus for the correct positioning of the distal locking screws of an intramedullary nail comprising a hole, the automatic pointing apparatus comprising:

means for receiving one or more images of a portion of the intramedullary nail to be fixed with the screws, the one or more images showing the hole;

means for processing the one or more images to obtain coordinates of the center of the hole and inclination of an axis of the hole;

means for positioning a surgical instrument in correspondence with the axis of said hole, and align the instrument with said axis;

a head which includes a reference system to be viewed by an X-ray, fluoroscopic or similar apparatus, the reference system comprising one or more radiopaque bodies of known shape, dimensions and position, incorporated in the head;

guidance means, included in said head, for guiding said surgical instrument;

means for moving said head close to an end of the nail comprising the hole,

means for taking, by said X-ray, fluoroscopic or similar apparatus, simultaneous images of the end of the nail comprising the hole for the distal locking screws and of the reference system;

means for reading the images and calculating position and inclination of the axis of the hole based on shape and dimensions of the hole shown in the images;

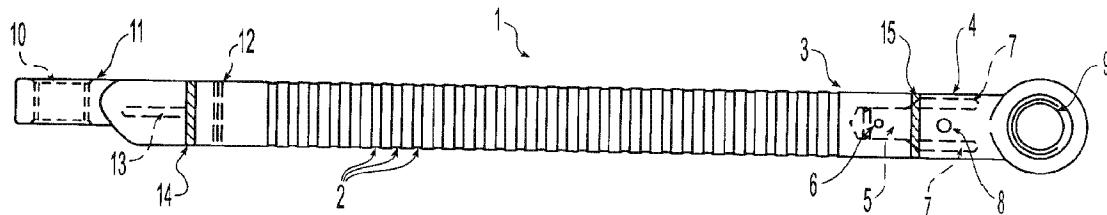
means for reading the images and calculating relative position and inclination of the reference system, and consequently of the head, based on shape and dimensions of the reference system;

means for calculating by a suitable algorithm position and inclination of the axis of the hole relative to the reference system;

means for moving the head so as to provide the means for guiding the surgical instrument with an inclination that is the same as the inclination of the axis of the hole. (Emphasis added).

Support for these amendments appears in, for example, at least original claims 2, 3, 5 and 7, the title, and paragraphs [0028], [0029], [0107] and [0108] of the description. Accordingly, no new matter is added.

Applicants submit that Wilson does not disclose, teach or suggest the features of amended claim 1. For ease of reference, Figure 1 of Wilson is depicted below.



Wilson, Fig. 1

Wilson relates to a radiolucent aiming guide for locating and drilling through the holes in the distal end of an implanted intramedullary nail. The aiming guide comprises an elongate handle constructed substantially of a

radiolucent material, which does not cast a strong image on a monitor when exposed to radiation. The radiolucent handle is used in conjunction with a protection sleeve, trocar, drill sleeve, and drill bit, which are used to locate and drill through the hole in the nail. Radiopaque components in the distal end of the protection sleeve, trocar, and drill bit are used to align the drill over the nail hole. A pair of radiopaque pins, located within the handle and lying parallel to its longitudinal axis, aid in ensuring the proper rotational alignment of the aiming guide over the nail hole. The aiming guide may also include a structure to facilitate its alignment over a second hole in the distal end of the intramedullary nail. (See Wilson: Abstract).

Applicant submits that Wilson does not disclose:

"means for reading the images and calculating position and inclination of the axis of the hole based on shape and dimensions of the hole shown in the images;

means for reading the images and calculating relative position and inclination of the reference system, and consequently of the head, based on shape and dimensions of the reference system;

means for calculating by a suitable algorithm position and inclination of the axis of the hole relative to the reference system;

means for moving the head so as to provide the means for guiding the surgical instrument with an inclination that is the same as the inclination of the axis of the hole"

as recited in claim 1. (Emphasis added).

Instead, Wilson discloses that a surgeon inserts the nail 61 into the medullary canal of the bone 60 across the area of the fracture. The X-ray source 70 and X-ray monitor 71 are positioned on either side of the area of the fracture. In particular, the X-ray source 70 is positioned so that hole 62 appears as a circle on the X-ray monitor 71, which indicates that the X-ray beam is parallel to the axis of hole 62. The part of the limb to be nailed is covered by a sterile radiation shield (not shown), except for the area directly above the distal holes in the intramedullary nail, which is left exposed. A scalpel or scissors (not shown) is

then positioned over the nail hole 62 so that the X-ray monitor 71 shows the image cast by the tip of the scalpel to fall within the image of the hole 62 of the intramedullary nail 61. An incision is then made over the first nail hole 62. The process is repeated to make an incision over the second nail hole 63. (See Wilson: column 5, line 61 through column 6, line10; Emphasis added). Wilson also discloses that the rotational alignment of the aiming guide can be checked by viewing the images cast by the pair of radiopaque pins 13 in the end portion 11 (or the pair of radiopaque pins 7, if end portion 4 is used instead). If the aiming guide is slightly rotated about the tip 23 of the protection sleeve 20, the distance between the images of the pair of radiopaque pins 13 will appear to expand or contract on the X-ray converter 71, as the protection sleeve 20 is brought into or out of alignment with the X-ray beam. When the images cast by the radiopaque pins 13 appear to lie on either side of and equidistant from the image of the nail 61, the surgeon will know that the longitudinal axes of the protection sleeve 20 and trocar 30 are properly aligned with the X-ray beam and thus with the nail hole 62. (See Wilson: column 6, lines 31-44; Emphasis added).

Applicants submit that, with such a disclosure, Wilson does not teach or suggest "means for reading the images and calculating position and inclination of the axis of the hole based on shape and dimensions of the hole shown in the images", and "means for reading the images and calculating relative position and inclination of the reference system, and consequently of the head, based on shape and dimensions of the reference system" and "means for calculating by a suitable algorithm position and inclination of the axis of the hole relative to the reference system", and "means for moving the head so as to provide the means for guiding the surgical instrument with an inclination that is the same as the inclination of the axis of the hole" as recited in claim 1. (Emphasis added). Wilson therefore does not disclose, teach or suggest all of the features recited in claim 1.

Furthermore, Applicant submits that Wilson also does not disclose an automatic pointing apparatus as recited in claim 1. Instead, Wilson teaches that the largest component of the handle 1 is the grip portion 3, into which are formed grooves 2 to improve the surgeon's hold on the aiming guide during surgery. The elongate shape of the handle 1 places the surgeon's hands at a safe distance away

from the area that is exposed to X-rays. (See Wilson: column 3, lines 61-64). Such a grip and elongate shaped handle not only does not disclose an "automatic pointing apparatus" as recited in claim 1, but teaches away from it.

For at least these reasons, Wilson does not disclose teach or suggest the features recited in claim 1. Therefore, claim 1 is patentable over Wilson.

Claims 2-3 are cancelled herein, rendering their rejection moot. Claim 4, by virtue of its dependency from claim 1, is patentable over Wilson for at least the same reasons as discussed with respect to claim 1.

Applicant respectfully requests withdrawal of the 35 U.S.C. §102 rejection for these claims.

35 U.S.C. §103

Claims 5-11 stand rejected under 35 U.S.C. §103 for allegedly being obvious in view of Wilson. Applicants note that claims 5 and 7 are cancelled herein. Claims 8-11 depend from amended independent claim 1. As previously discussed, Wilson does not disclose, teach or suggest the features in amended independent claim 1. Accordingly, amended claim 1 is neither anticipated by nor obvious in view of Wilson. Claims 8-11, by virtue of their dependency from claim 1, are also not obvious in view of Wilson.

Claims 8-11 are therefore patentable over Wilson, and a withdrawal of the 35 U.S.C. §103 rejection of these claims is respectfully requested.

CONCLUSION

Withdrawal of the rejections and allowance of the claims are respectfully requested.

The Commissioner is authorized to charge any additional fees which may be required or credit overpayment to deposit account no. 12-0415. In particular, if this response is not timely filed, then the Commissioner is authorized to treat this response as including a petition to extend the time period pursuant to 37 CFR 1.136 (a) requesting an extension of time of the number of months necessary to make this response timely filed and the petition fee due in connection therewith may be charged to deposit account no. 12-0415.

I hereby certify that this document is being transmitted to the Patent and Trademark Office via electronic filing.

January 6, 2012

(Date)

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